REMARKS

Claims 1, 3-4, and 11-27 are in this application. Claims 1, 3, 4 and 11-27 have been amended.

The Examiner has rejected claims 1-4 and 11-27 under 35 USC 112, second paragraph as being indefinite. Applicants respectfully traverse this rejection.

Claim 1 has been amended to delete the phrase "use in" , to include "comprising" instead of "including" and specifies that the growth factors and casein are maintained in the colostrum following fractionation of the colostrum. Growth factors are not introduced into the colostrum. Casein is not removed (or added) from the colostrum and is therefore, retained in the colostrum for use in a food composition.

Claim 4 has been amended to define the colostrum as being prepared by a ultra-filtration process to provide an ultra-filtered colostrum retentate .

Therefore, it is respectfully requested that this rejection be withdrawn.

The Examiner states that claims 1-4 and 11 are rendered vague and indefinite since it is unclear what is intended by "changing body composition and/or physical work capicity."

The definition of "physical work capacity" and "body composition" are provided on page 3 of the specification. A person skilled in the art would understand this terminology and the tests required to measure these changes. For instance, in standard sports medicine laboratories, changes in any of the parameters are often measured by standard tools and parameters such as heart rate monitors, distance travelled, speed etc. to determine exercise performance, recovery and reduction of fatigue. Similarly, physical parameters such as height, weight, body fat etc. are all measured using standard equipment.

The term "administering" is discussed on page 17 of the specification. One reading the specification and claims would understand that the food composition can be administered in various ways including orally, rectally or dermally. The Examiner's attention is also drawn to page 6, line 28 - page 7, line 4 where it is stated that the colostrum may be added to cream, milk, yoghurt, tonics, drinks, etc. One of ordinary skill in the art knows how to ingest these products.

The Examiner has objected to the term "physiological perception" in claim 14. Please explain that this would be a perception of well being as it applies to fatigue and can be measured using standard tests commonly used within practice.

Profile of Mood States (POMS) is a well known and validated measure of an individuals perceived level of their physiological state. It gives a profile of a persons mood which results from the combination of physiological and psychological phenomena. The BORG scale is another validated tool by which an individuals perceived level of exertion is measured. These two measures have been used in determining the effect of the food composition on each individuals own perception of their physiological state (mood and fatigue).

In claim 24, suitable amendments have been made in response to the Examiner's

suggestions. With respect to "peak power" and "peak performance", we advise that these are terms fully understood by the skilled addressee and are discussed in basic texts.

Peak power (force per unit time) was measured in units (Watts) which represents the amount of work (in joules) that can be done per second. Therefore, essentially the maximal rate was measured at which mechanical work could be done on the bike (i.e. if you are more powerful you do more mechanical work per unit time) and found that the food composition resulted in a significantly greater increase in this.

The vertical jump does the same thing. The vertical jump heights were converted to Watts and it was found that the food composition also increased vertical jump power more than the placebo.

With regard to claim 27, the claim has been amended to further clarify that the further compositions are made more accessible to the body.

The Examiner has objected to the term "improvement". This term is understood to be something that is better than it was before. The term is further discussed on page 3, lines 28 to 29. Clearly, an "improvement" can be measured by taking before and after treatment measurements and making the necessary comparisons. The definition of "physical work capacity" and "body composition" are provided on page 3. A person skilled in the art would understand this terminology and the tests required to measure their changes. For instance, in standard sports medicine laboratories, changes in any of the parameters are often measured by standard tools and parameters such as heart rate monitors, distance traveled, speed etc. to determine exercise performance, recovery and reduction of fatigue. Similarly, physical parameters such as height, weight, body fat etc. are all measured using standard equipment.

Therefore, it is respectfully requested that this rejection be withdrawn.

The Examiner has rejected claims 1-4 as being anticipated by Aalto. Applicants respectfully traverse this rejection.

This citation teaches ultrafiltration of colostrum but teaches to maintain the filtrate component of the ultrafiltration process, discarding the retentate. The filtrate is the component that passes through the membrane.

The present invention utilises a retentate which is retained by the membrane. However, the casein is also retained along with the immunoglobulins and growth factors. This component is then spray dried to provide the colostrum fraction for the food composition.

The Aalto reference clearly removes casein (the precipitate) in every example in order to produce what is described in the patent abstract as a "low endotoxin, protein and immunoglobulin preparation". Furthermore, in example 1 (upon which other examples all rely) it states that the whey was *incubated* and the precipitate (containing the casein) was removed by centrifugation. The whey is then ultrafiltered and the filtrate was used for subsequent processing steps and preparations. Again, this is essentially different to the samples used in the present application.

Accordingly, the citation by Aalto *et al* is directed toward the opposite fraction and

teaches that this component of colostrum has beneficial effects rather than the fraction which contains the casein and growth factors. The citation is therefore not relevant to the present application.

Therefore, it is respectfully requested that this rejection be withdrawn.

The Examiner has rejected claims 17-18 and 21-22 as being anticipated by Borody (AU-A-39340/89). Applicants respectfully traverse this rejection.

The claims objected by the Examiner rely on the use of a colostrum fraction to treat the gut. In the Borody *et al* citation, the use of hyperimmune colostrum or milk is described for the treatment of gut. The citation teaches on page 4 that milk is pasteurised at 62°C for 30 minutes. The present invention seeks to avoid the use of pasteurisation and specifically uses ultrafiltration to treat the colostrum. There is no mention of the removal of casein, nor of its importance in maintaining the component for treatment of the gut.

As described on page 5, last paragraph of the present application, casein may have beneficial properties for maintaining growth factors, particularly in the gastrointestinal tract. Compositions (as shown in the Aalto *et al* citation for instance) remove casein. In the present food compositions, the colostrum specifically maintains the casein having therefore a flow on and beneficial effect for the treatment of gut.

The prior art in Borody *et al* does not teach the same composition and therefore by reference to a different composition of claims 17 to 18, 21 to 22 are novel in the light of this citation.

Therefore, it is respectfully requested that this rejection be withdrawn.

In view of the amendment to claim 1, it is respectfully requested that the rejection under 35 USC 101 be withdrawn.

The Examiner has rejected claims 14, 16, 19 and 23-25 as being anticipated by WO 95/10192. Applicants respectfully traverse this rejection.

This citation relates to a nutritional drink containing colostrum. The product specifically teaches the precipitation and removal of casein from defatted colostrum for addition into a nutritional drink. In any case, where casein is not precipitated, the application continues to seek the use of the filtrate from an ultrafiltration process for use in the nutritional drink. On page 3 of the citation, there is ample discussion of the removal of casein in a precipitation step prior to filtration. The whey that is obtained is obtained as a filtrate. On page 4, there is discussion of the use of colostrum without previous removal of casein. However, ultrafiltration is again adopted to remove the casein. Accordingly, the colostrum as used in the nutritional drink has casein removed which again is a completely different composition to that used in the present application. Applicants submit that the claims are not identical to the cited reference, and therefore cannot be considered to be anticipated by the teachings of the cited reference. It is also clear from this citation that the nutritional drink had no positive improvement on performance compared to placebo (figure 5) and so would teach away from the use of colostrum for performance improvement.

Therefore, it is respectfully requested that this rejection be withdrawn.

The Examiner has rejected claims 11-13, 15, 20 and 26-27 as being anticipated by Clark (1996). Applicants respectfully traverse this rejection.

This citation discusses the use of colostrum in general for changing body composition, increasing tissue mass etc. as indicated by the Examiner. However, the colostrum used in Clark does not contain casein and therefore, by virtue of the objected claims being appended to claim 1, it includes the use of a colostrum which specifically maintains the casein. As described above, casein may have beneficial effects in the treatment of a number of conditions and this is not taught from the Clark citation. It is postulated that colostrum in general may provide these benefits, however, the specific composition provided in the application which is furthermore processed by a process which utilises the retentate as opposed to the filtrate will furthermore provide the beneficial effects outlined in claims 11 to 27.

Clark specifically states (p.15) that:

1. *" Colostrum which is water soluble is more easily assimilated. Colostrum which has been frozen cannot be made water soluble, and it must be specially micronized in order to be soluble".* Clark also states (p. 15) that unless the colostrum is water soluble *"you will not get the full benefits"*, and on p.16 *"Colostrum should be full* (sic) *water soluble".* This means that to get the full benefits of colostrum, Clark teaches the colostrum product made for use must not be frozen, be water soluble and specially micronized. The current composition does not employ a special micronizing process and so the results obtained would not be foreseen by Clark. Furthermore, casein is not water soluble. Casein exists in milk and colostrum as a colloidal suspension, and to be soluble requires the addition of an alkali. The current application specifically retains casein, which is not water soluble, and does not rely on the addition of an alkali at any stage. Clark therefore clearly teaches away from the current invention.

2. *"Some colostrum is manipulated to boost immunoglobulin levels. Recent research however, has shown that higher percentages of immunoglobulin actually diminish colostrum's effectiveness in combating infection".* The food composition of the current application has high and concentrated levels of immunoglobulins by the removal of some fat, lactose and minerals.

3. Clark also states (on p. 16) certain other pre-requisites for colostrum to be effective, including:

   a. *" .. if it isn't collected during the first 24 hours after the birth of the calf, it will be missing many of the important growth factors".* The food composition of the current application is not limited to colostrum from the first 24 hours after birth of the calf, and yet proves by chemical analysis and clinical effect that the important growth factors are available and efficacious.
   b. *"It should be filtered and homogenised to break down the long-chain proteins (immunoglobulins) for better assimilation".* The food composition of the current

application is not homogenised and is processed in a manner specifically to prevent any denaturation (breakdown) of the immunoglobulins and other proteins including growth factors.

c. *"It should be .... dried without added heat"*. The food composition of the current application is dried using added heat of a spray drying process. Clark teaches toward freeze-drying with subsequent micronization to help regain some solubility.

d. *"It should be laboratory tested for ... a verification of high platelet count (a sign of active friendly bacteria) ..."*. Platelets are blood cells. Blood is sometimes found in raw colostrum, and in the applicant's process is withheld from processing in order to meet safety standards and colour specifications in the final product.

It is clear that the current application disproves a number of the assertions made in the Clark citation and that the Clark citation cannot be seen to be relevant to the Food Composition described by the Applicants. Nowhere in the Clark citation is reference made to the importance of Casein as a component of colostrum products, and indeed by emphasising the importance of water solubility, teaches away from the retention of casein.

Therefore, it is respectfully requested that this rejection be withdrawn.

Applicants submit that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,

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1. A food composition for [use in] changing body composition and/or physical work capacity, said food composition [including] comprising colostrum or a fraction thereof wherein said fraction includes colostrum-derived growth factors and casein maintained [therein] within the colostrum following fractionation of the colostrum.

3. A food composition according to claim 1 [or 2] wherein the growth factor is IGF-1.

4. A food composition according to claims [2] 1 or 3 wherein [said casein is colostrum-derived and maintained therein following fractionation of the colostrum] the colostrum is prepared by a method comprising:

subjecting colostrum to an ultra-filtration process to provide an ultra-filtered colostrum retentate;

subjecting the ultra-filtered colostrum retentate to a spray drying process; and

removing the spray-dried colostrum.

11. A method of changing body composition and/or physical work capacity, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

12. A method of increasing tissue mass, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

13. A method of increasing fat utilisation, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

14. A method of reducing physiological fatigue and/or [physiological] an individual's perception of [that] their own fatigue, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

15. A method of increasing height, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

16. A method of increasing recovery after exercise, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

17. A method of treating or preventing a disorder of the gut, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

18. A method according to claim 17 wherein the disorder of the gut is selected from the group [including] consisting of mucositis, gastrointestinal damage from administration of non-steroidal anti-inflammatory drugs, gastrointestinal damage from irradiation therapy, gastrointestinal damage from chemotherapy, damage from infection in [normal] non HIV/AIDS and in HIV/AIDS patients caused by pathogens selected from the group including rotavirus, E. *Coli spp, Salmonella spp, Cryptosporidium spp, H. pylori,* damage from gut surgery, and damage due to disease including as crohn's disease, inflammatory bowel syndrome, coeliac disease, or cystic fibrosis.

19. A method of reducing muscle damage during exercise, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

20. A method of increasing physiological buffering capacity, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

21. A method of improving gut growth and development, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

22. A method of treating short bowel syndrome, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

23. A method of improving vertical jump performance, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

24. A method of improving the ability to generate peak power and peak force, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

25. A method of increasing endurance exercise performance, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

26. A method of reducing fat mass, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.

27. A method of improving the bioavailability of components in colostrum which lead to changed work capacity and/or body composition, said method [including] comprising administering an effective amount of a food composition according to [any one of claims 1 to 4 or 8 to 10] claim 1.